

Amendment No. 1 to HB2220

Sexton C
Signature of Sponsor

AMEND Senate Bill No. 2361

House Bill No. 2220*

by deleting all language after the enacting clause and substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 10, Part 1, is amended by adding the following as a new section:

(a) As used in this section, and unless the context otherwise requires:

(1) "Misbranding" means either the federal definition under 21 U.S.C. § 352 or drugs or devices that are misbranded under § 53-10-106; and

(2) "Off-label" means the use of an United States Food and Drug Administration ("FDA")-approved drug, biological product, or device other than the use or uses approved by the FDA.

(b)

(1) A pharmaceutical manufacturer or its representatives may engage in truthful promotion of off-label uses.

(2) This section does not require a health insurance entity, as defined in § 56-7-109, other third-party payer, or other health plan sponsor to provide coverage for the cost of any off-label treatment. A health insurance entity, other third-party payer, or other health plan sponsor may provide coverage for an off-label treatment.

(c)

(1) Notwithstanding any other law, no official, employee, or agent of this state shall enforce or apply § 53-10-106(a)(2) against or otherwise prosecute a

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pharmaceutical manufacturer or its representatives for engaging in truthful
promotion of off-label uses.

(2) Notwithstanding any other law, no state regulatory board may revoke,
fail, or renew or take any other action against a pharmaceutical manufacturer's or
representative's, healthcare institution's, or physician's license solely for
engaging in truthful promotion of off-label uses.

SECTION 2. This act shall take effect July 1, 2018, the public welfare requiring it.